HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service
Food and Drug Administration
New Orleans District
Southeast Region
4298 Elysian Fields Ave.
New Orleans, LA 70122

Telephone: 504-589-6341
FAX: 504-589-6360

May 21, 1999

WARNING LETTER NO. 99-NOL-31

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Wesley A. Miley, President
Home Oxygen and Medical Equipment, Inc.
393-C Crossgates Boulevard
Brandon, MS 39042

Dear Mr. Miley:

During an inspection of your manufacturing facility, located at 393-C Crossgates Boulevard, Brandon, Mississippi, conducted on April 6 - 15, 1999, our investigator documented deviations from the Current Good Manufacturing Practice (CGMP) regulations. These deviations cause your drug product, Oxygen, U.S.P., to be adulterated within the meaning of 502(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act). The controls used for, manufacture, processing, packing or holding of this product are not in conformance with Current Good Manufacturing Practice regulations (Title 21, *Code of Federal Regulations*, Parts 210 and 211).

Our inspection revealed the following CGMP deficiencies:

1. Failure to provide training to employees involved in the transfilling of medical oxygen;

2. Failure to establish written procedures for training, acceptance specifications of incoming and finished product, Oxygen, U.S.P., routine maintenance of oxygen concentrators, establishing a Quality Control Unit and calibration schedules for transfilling equipment;

3. Failure to perform an odor test on the cylinder of Oxygen, U.S.P., tested after filling;

4. Failure to leak-test filled cylinders of Oxygen, U.S.P., prior to release;

5. Failure to monitor cylinder temperature during transfilling;

6. Failure to perform appropriate pre-fill operations on cylinders in that the hammer test was performed on aluminum cylinders;

7. Failure to perform required checks of the dryer tube and filter of the Servomex Analyzer used for the assay of Oxygen, U.S.P.;

8. Failure to properly calibrate the vacuum gauge used for the transfilling of Oxygen, U.S.P.;

9. Failure to perform the required routine maintenance of your firm's oxygen concentrators;

10. Failure to establish a quality control unit;

11. Failure to document date of testing of incoming Oxygen, U.S.P.; and,

12. Failure to document approval of your written procedures for oxygen transfilling operations.

The above identification of violations is not intended to be an all-inclusive list of deficiencies. It is your responsibility to assure adherence with each requirement of the Current Good Manufacturing Practice regulations. Federal agencies are advised of the issuance of warning letters about drugs and devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to properly correct them may result in regulatory action without further notice. This may include seizure and/or injunction.

We are aware that at the close of the inspection you made a verbal commitment to correct the observed deficiencies. However, it is necessary that you notify this office in writing, within 15 days of the receipt of this letter, of the steps that you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for this delay and the time within which the corrections will be completed.

Your response should be directed to Nicole F. Hardin, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana 70122, telephone number 504-589-7166. Should you have any questions concerning the contents of this letter, or if you desire a meeting with the agency staff, please contact Ms. Hardin.

Sincerely,

Carolyn S. Olsen

for James E. Gamet
District Director
New Orleans District

Enclosure: FDA 483